

Remarks:

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1-73 are now in the case. The paragraph beginning on page 3 at line 14 of the Specification has been amended. Claims 8, 9, 10, 12, 13, 17, and 20 have been amended.

Applicants assert that the present amendments add no new matter. Basis for the amendment to Claims 17 and 20 is provided in the Specification as originally filed. Specifically, antecedent basis for claim language comprising an “antibody or antibody fragment” is provided in Claim 15. Basis for the other amendments is provided below.

Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

OBJECTIONS TO SPECIFICATION

The Specification has been objected to as indefinite, regarding page 3, lines 20-21, “Illustrative polypeptides include polypeptides comprising either amino acid residues SEQ ID NO:3 or amino acid residues SEQ ID NO:3.” Line 21 of page 3 has been amended to replace the first “SEQ ID NO:3” with “of 18-228 of SEQ ID NO:2”. Basis for this amendment can be found in the Specification as originally filed. Specifically, according to page 3, lines 17-18, residues 18-228 of SEQ ID NO:2 are “shown as SEQ ID NO:3”.

OBJECTIONS TO CLAIMS

Claims 8, 9, 10, 12, and 13 are objected to for depending from non-elected Claim 1. Applicants have amended Claim 8 to independent form and to incorporate the elements of non-elected Claim 1.

Claims 9 and 10 were dependent to Claim 2 that is dependent to Claim 1. Applicants have amended Claims 9 and 10 to add dependence to Claim 8 and to incorporate the elements of non-elected Claim 2.

Claims 12 and 13 were dependent to Claim 5 that is dependent to Claim 1. Applicants have amended Claims 12 and 13 to add dependence to Claim 8 and to incorporate the elements of non-elected Claim 5.

Claims 56 and 57 are objected to for depending from Claim 55 as containing non-elected subject matter. **Applicants traverse.** Applicants understand that Claim 55 encompasses non-elected species. However, Applicants have elected the species of a polypeptide consisting of the amino acid sequence of SEQ ID NO:3 from amino acid number 1 (Pro), to amino acid number 6 (Asp). According to MPEP 803.02, when the Examiner requires a species election among the elements of a Markush-type claim, “Following election, **the Markush-type claim will be examined fully with respect to the elected species** and further to the extent necessary to determine patentability.” (emphasis added). The MPEP **does not** require Applicants to amend a Markush-type claim by narrowing it to an elected species prior to examination of that elected species. Therefore, while Claims 56 and 57 are dependent to Claim 55 generally, **Claims 56 and 57 are currently being examined fully only with respect to the elected species.** Accordingly, Applicants request that the Examiner withdraw the objection to Claims 56 and 57.

Applicants are aware that Claim 8 as amended encompasses non-elected species. However, Applicants have elected the species of a polypeptide consisting of the amino acid sequence of SEQ ID NO:3 from amino acid number 1 (Pro), to amino acid number 6 (Asp). As above, Applicants point out that the MPEP does not require Applicants to amend a Markush-type claim by narrowing it to an elected species prior to examination of that elected species. While Claims 9-15 are dependent to Claim 8 generally, they are currently being examined fully only with respect to the elected species.

REJECTIONS UNDER 35 U.S.C. §103(a)

Regarding the 35 U.S.C. §103(a) rejection under Busfield in view of Hopp et al.

Claims 8-10, 12, 13, 15-18, 20, 21, 55-57 and 59 have been rejected under 35 U.S.C. §103(a) as unpatentable over US Patent Application No. 02-0164689 (Busfield) in view of Hopp et al. (PNAS 78: 3824-3828, 1981). The Action alleges that it would have been *prima facie* obvious to one skilled in the art to make an antibody against a peptide from the polypeptide with SEQ ID NO:2, based on Busfield. It is further alleged that one skilled in the art would have been motivated to choose the hexapeptide PEDPSD with reasonable expectation of success based on the teachings of Hopp et al.

Applicants traverse. The Examiner has failed to establish that the present Application is *prima facie* obvious based on Busfield in view of Hopp et al. Three criteria must be met to establish *prima facie* obviousness. The first is that

[T]here must be some suggestion or motivation, either in the references themselves or in knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings...

MPEP 706.02(k) and MPEP 2143. Or, stated more succinctly as to the present rejection,

It is improper to combine references where the references teach away from their combination.

MPEP 2145 citing *In re Grasselli*, 713 F.2d 731 743 (Fed. Cir. 1983).

Busfield teaches away from Hopp et al. Therefore, it is improper to combine the two. The Examiner cites Hopp et al. to show that the antigenic hexapeptide fragment claimed in the present Application is obvious because one having ordinary skill in the art would understand that “the best antigenicity is obtained using hexapeptides (p. 3826 – Table 3) and especially peptides rich in P, E and D (p. 3826 – Table 2).” Office Action dated 8/18/2006 (emphasis added). However, Busfield teaches away from the proposition that the best antigenicity is obtained using hexapeptides: Busfield teaches that antigenic peptide fragments should

... comprise at least 8 (preferably 10, 15, 20, or 30) amino acid residues of the amino acid sequence of SEQ ID NO:2...

Busfield, paragraph [0169] (emphasis added). Therefore, one having ordinary skill in the art would not assume that the best antigenic fragments in the sequences disclosed in Busfield are hexapeptides (as disclosed in Hopp et al.); rather, one having ordinary skill in the art would assume that the best antigenic fragments should be longer, “at least 8 (preferably 10, 15, 20, or 30) amino acid residues” long. *Id.* Accordingly, Busfield teaches away from Hopp et al. so the two cannot properly be combined, and the Examiner has failed to establish that the present invention is *prima facie* obvious over Busfield in view of Hopp et al.

With further regard to the 35 U.S.C. §102(a) rejection based on Busfield in view of Hopp et al.

The Examiner has also failed to meet the third criteria necessary to show that the present invention is *prima facie* obvious. Specifically, the third element of *prima facie* obviousness is that “the prior art reference (or references when combined) must **teach or**

suggest all the claim limitations.” See MPEP 706.02(k); MPEP 2143; and MPEP 2143.03 *citing In re Royka*, 490 F.2d 981 (CCPA 1974) (emphasis added). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” MPEP 2143.03 *citing In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) (emphasis added).

The Claims of the present Application incorporate the limitation that the antibody should reduce and/ or neutralize the activity and/ or pro-inflammatory activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO:6). This limitation is not disclosed in either of Busfield or Hopp et al. Accordingly, any combination of the two references is insufficient to render the present invention *prima facie* obvious.

Based on the arguments presented above, Applicants respectfully request that the Examiner withdraw the current 35 U.S.C. §103(a) rejection of Claims 8-10, 12, 13, 15-18, 20, 21, 55-57 and 59, based on Busfield in view of Hopp et al.

Regarding the 35 U.S.C. §103(a) rejection under Lok et al. in view of Hopp et al.

Claims 8, 9, 12, 15-17, 20, 55-57 and 59 have been rejected under 35 U.S.C. §103(a) as unpatentable over US Patent No. 5,965,704 (Lok et al.) in view of Hopp et al. (above). The Action alleges that it would have been *prima facie* obvious to one skilled in the art to make an antibody against a peptide from the polypeptide with SEQ ID NO:2, based on Lok et al. It is further alleged that one skilled in the art would have been motivated to choose the hexapeptide PEDPSD with reasonable expectation of success based on the teachings of Hopp et al.

Applicants traverse. The Examiner has failed to establish that the present Application is *prima facie* obvious based on Lok et al. in view of Hopp et al. Three criteria must be met to establish *prima facie* obviousness. The third is that “the prior art reference (or references when combined) **must teach or suggest all the claim limitations.**” See MPEP 706.02(k); MPEP 2143; and MPEP 2143.03 *citing In re Royka*, 490 F.2d 981 (CCPA 1974) (emphasis added). “**All words in a claim must be considered** in judging the patentability of that claim against the prior art.” MPEP 2143.03 *citing In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) (emphasis added).

The Claims of the present Application incorporate the limitation that the antibody should reduce and/ or neutralize the activity and/ or pro-inflammatory activity of either IL-20 (SEQ ID NO:8) or IL-22 (SEQ ID NO:6). This limitation is not disclosed in

either of Lok et al. or Hopp et al. Accordingly, any combination of the two references is insufficient to render the present invention *prima facie* obvious.

Therefore, Applicants respectfully request that the Examiner withdraw the current 35 U.S.C. §103(a) rejection of Claims 8, 9, 12, 15-17, 20, 55-57 and 59, based on Lok et al. in view of Hopp et al.

Regarding the 35 U.S.C. §103(a) rejection under Busfield or Lok et al. in view of Hopp et al. and in further view of Chen et al.

Claims 11, 14, 19, 22, 58, and 60, have been rejected under 35 U.S.C. §103(a) as unpatentable over either Busfield or Lok et al. in view of Hopp et al. and further in view of Chen et al. (Biodrugs 15(12):833-847, 2001). The Action alleges that it would have been obvious to one skilled in the art to modify the antibodies by PEGylation based on either Busfield or Lok et al. in view of Hopp et al. in order to increase the serum half-life, as taught by Chen et al.

Applicants traverse. The MPEP instructs that

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim dependent therefrom is nonobvious.

See MPEP 2143.03 *citing In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). In the arguments presented above, Applicants have shown that independent Claims 8, 15, 55, and 66, are non-obvious over either Busfield or Lok et al. in view of Hopp et al. Accordingly, the Claims dependent therefrom (including Claims 11, 14, 19, 22, 58, and 60) are likewise nonobvious over either Busfield or Lok et al. in view of Hopp et al.

Therefore, Applicants respectfully request that the Examiner withdraw the current 35 U.S.C. §103(a) rejection of Claims 11, 14, 19, 22, 58, and 60, based on Busfield or Lok et al. in view of Hopp et al. and in further view of Chen et al.

CONCLUSION

On the basis of the above amendments and remarks, Applicants believe that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

The requisite fee for Extension of Time is enclosed. It is believed that no other fee is due. However, in the event that another fee is due, please charge any fee or credit any overpayment to Deposit Account No. 26-0290.

Respectfully Submitted,



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Enclosures:

Petition and Fee for Extension of Time

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ZymoGenetics, Inc.